Acquisition of Medical Countermeasures (MCMs) for Pandemic Influenza Preparedness and Response

Section C: STATEMENT OF WORK

BACKGROUND:

The potential for a human influenza pandemic continues to be a public health concern. Four influenza pandemics occurred over the last century. In 2009, we completed the preparation and response to the most recent pandemic caused by the H1N1 virus. Sporadic infections of humans with avian influenza viruses with high mortality (H5N1, H7N9) suggest the public is at risk for a severe influenza pandemic. An outbreak of severe pandemic influenza could cause over 60 million deaths worldwide by some estimates.

Pillar One of the National Strategy for Pandemic Influenza (2005) describes the activities to be undertaken before a pandemic to ensure preparedness. The strategy seeks to "establish domestic production capacity and stockpile of countermeasures to ensure sufficient vaccine to vaccinate front-line personnel and at-risk populations". In the Implementation Plan for the National Strategy for Pandemic Influenza (2006) two primary goals were set "(1) establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat; and (2) expansion of domestic influenza manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration." To accomplish these goals, the Federal Government established stockpiles of influenza countermeasures, as well as domestic vaccine manufacturing capacity. In addition substantial new investments were made in the advanced development of cell-culture-based influenza vaccine candidates, with a goal of establishing the domestic surge vaccine production capacity to meet the pre-pandemic stockpile and post-pandemic vaccine production goals."

On December 2009 Secretary Sebelius called for the Public Health Medical Countermeasure Enterprise Review which was issued in August 2010 and stated: "The ultimate goal of this review is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. In other words, we want to create a system that can respond to any threat at any time."

Vaccination remains the primary countermeasure against pandemic influenza. Supporting the need for ongoing acquisition of novel subtypes of influenza, currently licensed vaccines for influenza are virus subtype specific. It remains uncertain which influenza subtype will cause the next pandemic. As a result, the ability of vaccines in the National Pre-pandemic Influenza Vaccine Stockpile to protect against emerging strains of influenza is unknown.

The current contracts for "Acquisition of MCMs for Pandemic Influenza Preparedness and Response" awarded in 2012 to five manufacturers expire in September 2015. It is critical, therefore to award contracts to manufacturers for this program in order to

guarantee continuity of the influenza pandemic preparedness and response capabilities and to maintain current stockpiled vaccines and adjuvants.

The 2009 H1N1 influenza pandemic demonstrated how crucial it is to have active contracts with manufacturers to respond to an influenza pandemic event; in 2009 the Federal Government rapidly modified existing stockpile contracts and issued task orders to manufacturers to produce millions of doses of H1N1 influenza vaccine.

This program will serve as a continuation and expansion of the US Pandemic Preparedness Plan which currently includes contracts with five influenza vaccine experienced companies. The competition will be open to companies that are currently licensed for inactivated, recombinant and live attenuated influenza vaccine (LAIV), both seasonal and pandemic. In addition, competition is open to Offerors that demonstrate a successful experience in the manufacturing of influenza vaccines at commercial scale, have completed Phase 3 clinical studies (including a final Clinical Study Report) for influenza vaccines with a documented US BLA in preparation for an influenza vaccine.

SCOPE OF WORK:

Independently and not as an agent of the US Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described below.

The Contractor shall provide Medical Countermeasures (MCMs) for Pandemic Influenza Preparedness and Response or as required in response to a HHS designated Public Health Emergency. The contractor shall produce vaccines against influenza and influenza strains with pandemic potential; shall demonstrate a successful experience in the manufacturing of influenza vaccine by:

- Holding a US influenza vaccine license **OR**
- Have developed an influenza vaccine as evidenced by:
    - A pivotal Phase 3 final clinical study report **AND**
    - Minutes from an US FDA Pre-BLA meeting

Detailed Description of CLINs:

CLIN 0001: cGMP Influenza Vaccine Master and Working Seed Lot

The Contractor shall provide yield optimized master and working **seed lots** for inactivated, live attenuated or recombinant influenza vaccine product.

The unit for this item will be a **seed lot**.

The Contractor shall:

- Manufacture Master and Working seeds lots for influenza vaccine using the same facilities, systems, equipment, processes and testing as those described and referenced in the FDA-licensed influenza vaccine or as described in the BLA in preparation, according to current Good Manufacturing Practices (cGMP) under

21 CFR parts 210, 211, and 600, as applicable and store at appropriate conditions during lot release testing.

- Manufacture the seed lot using the qualified influenza candidate vaccine virus (CVV) reference strain as specified by HHS.
- Provide lot release product testing of the influenza seed lot using lot release specifications of the FDA-licensed influenza product, or the in-process BLA filing.
- Provide seed lot samples to the FDA for identity verification, and other testing as specified by HHS.
- Store seed lots according to FDA cGMP guidelines.
- Conduct stability or other testing as appropriate.
- Add manufactured seed lots to ongoing inventory reports and controlled storage.
- Submit standard data report 'MN001' according to instructions in 'Reporting Requirements' and 'Attachment "A".
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0002: Influenza Vaccine Development Lot(s)

The Contractor shall provide an influenza vaccine **small scale, development lot**.

The unit for this item will be a **development lot**.

The Contractor shall:

- Provide data derived from the manufacturing process.
- Provide a final report including, at minimum, the information in the final report requirements table. (See Table 1)

CLIN 0003: cGMP Influenza Vaccine: Clinical Lot(s)

The Contractor shall provide influenza vaccine clinical lot(s).

The unit for this item will be a **clinical lot**.

The Contractor shall:

- Manufacture the clinical vaccine lot in manufacturing facilities according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or BLA under preparation.
- Perform lot release product testing of the influenza vaccine using lot release specifications of the FDA-licensed influenza vaccine product or described in the BLA document in preparation. Provide results to HHS.
- Make batch records available for review by HHS.
- Set aside samples for stability testing up to 120 months.

- Upon Request, submit standard data reports according to instructions in 'Reporting Requirements' and 'Attachments."
- Provide a final report including, at minimum, the information identified in the Final Report Requirements. (See Table 1).

CLIN 0004: cGMP Influenza Vaccine: Commercial Scale Bulk Lot(s)

The Contractor shall provide **influenza vaccine bulk** product.

The unit for this item will be a **bulk lot** The Contractor shall:

- Manufacture the commercial scale bulk vaccine lot in manufacturing facilities according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or BLA under preparation.
- Perform lot release product testing of the influenza vaccine including potency using lot release specifications of the FDA-licensed influenza vaccine product or described in the BLA document in preparation. Provide results to HHS.
- Set aside samples for stability study testing for up to 120 months. Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.
- Conduct lot release product testing of the influenza bulk vaccine according to the licensed (or in-process BLA documented) product. Provide results to HHS. Make batch records available for review by HHS.
- Submit standard data report 'MN004' according to instructions in 'Reporting Requirements' and 'Attachment "A".
- Provide a final report including, at minimum, the information identified in the Final Report Requirements (See Table 1).

CLIN 0005: cGMP Adjuvant: Commercial Scale Bulk Lot(s)

The contractor shall provide **adjuvant** bulk product suitable for formulation and filling. Proposed adjuvant shall have completed Phase 2 development in combination with a pandemic or pre-pandemic antigen. Clinical evidence of antigen sparing and/or adjuvant benefit for the pandemic or pre-pandemic antigen is required.

The unit for this item will be a **bulk lot** The Contractor shall:

- Manufacture the bulk adjuvant product at commercial scale according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing.
- Make available batch records for review by HHS.
- Set aside samples for stability study testing for up to 120 months Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.

- Execute lot release product testing of bulk adjuvant.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements' and 'Attachments."
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table XX.

CLIN 0006: Formulation and Filling

The unit for this item is **each**.

The contractor shall:

- Formulate and fill influenza antigen and/or adjuvant in final containers specified in CLIN 0006 A-H.
- Formulation, fill-finish activities of vaccine and adjuvant shall be carried out at facilities in compliance with FDA-cGMP guidelines and if applicable, in accordance with the formulation and filling requirements that apply to FDA-licensed influenza vaccine product unless otherwise requested, specified and approved by HHS.
- Formulate material at the concentration or dosage determined by HHS.
- Fill each unit to a volume determined by HHS.
- Assure compliance of formulation and filling activities with the license or in-process BLA documentation as required by HHS.
- Assure compliance of filling activities with relevant FDA cGMP guidelines.
- Execute lot release product testing of the final container using lot release specifications of the FDA-licensed influenza vaccine product or in-process BLA.
- Affix labels onto filled final containers with HHS approved text. HHS may require coding on primary containers and secondary packages for product identification, serialization, lot number and expiration dating in accordance with FDA and GS1 / ISO standards.
- Package filled and labeled final containers as required/specified by HHS.
- Set aside final containers for stability study testing for up to 120 months Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.
- Submit standard data report 'MN007' according to instructions in 'Reporting Requirements' and 'Attachment "A".
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0006A: *Antigen: Single dose vials*

CLIN 0006B: *Antigen: Syringes or sprayers*

CLIN 0006C: *Antigen: Multi-dose vials*

CLIN 0006D: *Adjuvant: Single dose vials*

CLIN 0006E: *Adjuvant: Multi-dose vials*

CLIN 0006F: *Co-formulated antigen and adjuvant: Single dose vials*

CLIN 0006G: *Co-formulated antigen and adjuvant: Syringes*

CLIN 0006H: *Co-formulated antigen and adjuvant: Multi-dose vials*

CLIN 0007: Storage and Stability

The Contractor shall:

- Provide temperature controlled storage for up to sixty (60) months at the Contractor site approved by HHS, according to cGMP and the Contractor's product specifications.
- Store bulk lots and final containers physically segregated from other products
- Ensure proper labeling of stored materials as USG property.
- Execute stability testing of stored material in a manner consistent with the stability testing plan approved by HHS. Report interim data and results to HHS on a monthly basis.
- Ensure sufficient representative samples are available at the time of 'Storage and Stability' task order award for stability testing for 120 months from the date of manufacture.
- Ensure stored materials are compliant with the Contractor's internal quality control system and are ready for use in further cGMP governed manufacturing of clinical material or licensed doses as directed by HHS.
- Provide the government access to review the security system in place and request updates as needed.
- Include in monthly report inventory (lot number, number of lots, number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).
- Ensure that material being relocated for the contractors' convenience is adequately insured at no cost to the government and with CO approval.
- Conduct testing necessary to ensure continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.

- Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
- If using a subcontracted storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by HHS.
- Submit standard data reports 'MN014' and 'MN017' according to instructions in 'Reporting Requirements' and 'Attachment "A".
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0007A: Storage of clinical bulk lots of antigen

The unit for this item is a **lot-month,** which equals a one (1) month of storage and stability for one (1) lot.

CLIN 0007B: Storage of commercial bulk lots of antigen

The unit for this item is a **lot-month,** which equals one (1) month of storage and stability for one (1) lot.

CLIN 0007C: Storage of antigen in final container

The unit for this item is a **final container-month,** which equals a single (1) month of storage and stability for a single (1) final container.

CLIN 0007D: Storage of adjuvant bulk

The unit for this item is a **lot-month,** which equals a single (1) month of storage and stability for a single (1) lot.

CLIN 0007E: Storage of adjuvant in final container

The unit for this item is a **final container-month,** which equals a single (1) month of storage and stability for a single (1) final container.

CLIN 0007F: Storage of licensed product in final package

The unit for this item is a **package-month,** which equals a single (1) month of storage and stability for a single (1) package.

CLIN 0008: Shipping

The unit for this item is **each**.

The Contractor shall:

- Package, handle and ship material to the destination specified in the RTOR.
- Arrange for transit, delivery and insurance of material shipped. Send EDI 856 Advanced Shipping Notices upon request.
- Be responsible for delivering material shipped in a condition fit for its intended use.

- Provide program and contracting offices with completed BARDA shipping form (See attachment).
- Submit standard data report 'DM002' according to instructions in 'Reporting Requirements' and 'Attachment "A".
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0009: Candidate Vaccine Virus (CVV)

The Contractor shall:

- prepare non-GLP and/or GLP influenza candidate vaccine viruses using high yield donor viruses or genes as directed by HHS and specified in the RTOR.
- Perform characterization and *in vitro* and *in vivo* bio-safety level testing as necessary.

CLIN 0010: Potency reagent and standards manufacture and testing

The Contractor shall provide influenza vaccine reagents and standards.

The unit for this item is **each**.

The Contractor shall:

- As directed by HHS, execute activities related to reagent and standards manufacture and testing including purified HA for antibody production, primary liquid standard antigen reference, secondary antigen reference and antibody production.
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0011: Laboratory Testing/Assay

The unit for this item will be **each**.

The contractor shall:

- Laboratory testing/assay as required by HHS and specified in the RTOR
- Provide a final report. The requirements will be provided in the RTOR.

CLIN 0012: Animal Studies

The unit for this item is **study**.

The Contractor shall:

- Animal studies as as required by HHS and specified in the RTOR.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements' and 'Attachments.'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements. (See Table 1).

CLIN 0013: Clinical Studies

The unit for this item is **study**.

- Clinical studies as required by HHS and specified in the RTOR.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements' and 'Attachments."
- Provide a final report including, at minimum, the information identified in the Final Report Requirements. (See Table 1).

CLIN 0014: Disposal of product

The unit for this item is **each**.

The Contractor will dispose of all products related to this contract, as required by the USG.

The Contractor shall:

- Dispose of product following all federal and state regulations for the appropriate waste category; hazardous waste (thimerosal-containing vaccines), regulated medical waste (LAIV), solid waste (non thimerosal-containing vaccine, non LAIV).
- Provide documentation and reports on the performed and completed disposal activity.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements' and 'Attachments."
- Provide a final report including, at minimum, the information identified in the final report requirements table. (See Table 1)

CLIN 0015: BARDA Tracking Tool-Development and Testing of New Standard Data Reporting Formats

The unit for this item is **each**.

The Contractor shall:

- Plan and create new data sets for submission to the BARDA Tracking Tool (BTT) as described by contract and/or RTOR. These are additive to the data sets identified in Section F 'Reporting Requirements and Deliverables' For planning purposes, BARDA is considering the following data sets for new development and testing with the BARDA Tracking Tool and may add other data sets in the future.

Data Set	Description	Aligns with CLIN #
MN005	Production of Bulk Adjuvant Lots	CLIN #0005
MN008	Formulation, Fill and Finish of Adjuvant Lots	CLIN #0006D and 0006E
MN009	Storage of Bulk Drug Substance	CLIN #0007B

MN010	Storage of Bulk Adjuvant Lots	CLIN #0007D
MN012	Storage of Clinical Lots	CLIN #0007A
MN013	Storage of Final Drug Product	CLIN #0007E and 0007E
DS002	Disposal of Bulk Drug Substance	CLIN #0015
DS006	Disposal of Final Drug Product	CLIN #0015

- Conduct testing and validation of new data sets submitted to the BARDA Tracking Tool (BTT) Program as described by contract and/or RTOR. Guidance and instructions regarding new data sets (types of data, what to submit, when to submit, how to submit, frequency of submission) will be provided in the RTOR.
- Upon validation, submit new data set on a recurring basis to the BTT for all materials that are currently under contract and/or incorporated from previous contracts. New data sets, upon validation, become part of Standard Data Report baseline.
- For additional information on the current baseline requirements please review Section F 'Reporting requirements and Deliverables' and 'Attachment "A".

CLIN 0016: Additional Reporting

The unit for this item is **report**.

The Contractor shall:

- Submit inventory reports, monthly progress reports, executive summaries, *ad hoc* reports of urgent developments related to this program and a final report as described in detail in the Reporting Requirements and Deliverables. Provide a final report including, at minimum, the information identified in the final report requirements table. (See Table 1)
- In Q1 of each calendar year, submit an updated table describing facility availability to complete all CLIN activities throughout the year. A template will be provided by the CO for completion.
- Respond to information requests from HHS pertaining to the ongoing activities.
- Inform the CO and COR of all issues involving any of the material managed under this contract within three (3) business days of the incident. An impact assessment and remediation plan shall be provided within twenty (20) business days of the incident.
- Provide copies of reports from regulatory inspections of facilities proposed under this contract for the completion of CLIN work to the CO and COR within five (5) business days of the inspection or receipt of the report. Provide warning letters to the CO and COR within five (5) business days of receipt.

- Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses. Submit documentation of regulatory update(s) with the monthly report.
- Provide regulatory documentation as required by HHS.

Additional Requirements

Except where explicitly identified, 'HHS' refers to HHS/ASPR/BARDA/ID and HHS/ASPR/AMCG.

The complete Phase 3 clinical study report to document manufacturer's eligibility must be ready for submission to the FDA with no modifications.

Alternative potency assays may be used when CBER reagents are not available and must be approved by the CO. When reagents become available, potency determination should be bridged to SRID testing. Parallel testing with both assays shall continue for the duration of the stability program.

It is the preference of HHS that the Contractor manufacture bulk vaccines and bulk adjuvant in the US. When a Contractor manufacturers outside the US, manufactured material shall be shipped to the US within 60 days of lot release. An exception to this requirement may be requested from HHS. Shipment of the vaccine or adjuvant to the US shall be coordinated with HHS and other offices/agencies involved in importation of vaccines. Importation of bulk vaccine and adjuvant into the US may require testing which shall be performed according to applicable federal guidelines (FDA, USDA, CDC). The Contractor shall bear all costs for shipping and testing required for import into the US. This requirement can be unilaterally modified by HHS during a public health emergency to allow for international formulation and filling prior to shipment to the US. If the contractor has domestic/international facilities for primary and secondary manufacturing or storage, products must be shipped from/to different facilities at no cost to the US government.

Bulk manufacturing facilities shall be in compliance with appropriate biosafety level bio-containment procedures.

Contractors holding a US license for an influenza vaccine shall perform all activities described in the CLINs according to those of their FDA-licensed influenza vaccine product processes, including but not limited to the same facilities, systems, equipment processes and testing as for the licensed product. In lieu of a licensed processes, Contractors with unlicensed influenza vaccine products that have completed the final clinical study report for their Phase 3 trial and are preparing the BLA shall perform all activities described in the following CLINs using the same facilities, systems, equipment, processes, and testing as those described in the BLA document in preparation. Only Contractors without a licensed influenza vaccine may use unlicensed processes to perform work described in the CLINs. Contractors that receive licensure during the course of this contract are required to use the licensed processes for the duration of the contract and to ensure that materials previously purchased by Gov't from

vendor prior to license are compliant with the licensed process, to the extent practical or reasonable with HHS approval.

Products manufactured and stored under this contract are 'Government Furnished Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.

When appropriate, contractors shall use the same validated facilities, systems, equipment, and manufactured processes for cGMP manufacturing of licensed influenza vaccine and adjuvant product or influenza vaccine and adjuvant product with an in-process BLA.

When appropriate, contractors shall use the same validated and approved assays and equipment for lot release of influenza vaccine product and final container influenza vaccine products and stability studies.

When appropriate, contractors shall use the same validated facilities, systems, and equipment suitable for cGMP storage of influenza vaccine and adjuvant products.

Provide the government access to review the security system in place and request updates as needed.

When appropriate, contractors shall use the approved facilities, equipment, and policies to receive, store, utilize, and dispose of bio-hazardous materials in appropriate conditions (e.g. Biosafety Level 2+ as appropriate).

As appropriate, contractors shall employ approved biosafety measures compliant with WHO biosafety guidelines for influenza vaccine including protective garments, equipment, sufficient monitoring to assure safe handling of potentially hazardous materials for the safety and protection of workers. Contractors shall conduct work under the contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions.

Notification shall be given to US Government prior to any disposal of material, records, documentation, and/or reports for consultation and disposition.

The Contractor shall allow HHS-designated personnel including BARDA staff to perform on-site auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS.

In case of a pandemic event, HHS staff and/or designees will be on the Contractor's site to monitor daily activity and progress under the terms of the contract and facilitate discussion between the Contractor and HHS.

In case of a pandemic event, the contractor must submit a detailed production and delivery schedule for bulk vaccine, bulk adjuvant, and final containers as soon as task orders and delivery orders are received.

Contractors must submit documents as requested to support the preparation of a pre-EUA document for their vaccine or adjuvant by HHS.

Section F: REPORTING REQUIREMENTS AND DELIVERABLES

The Contractor(s) shall submit to the Contracting Officer (CO) and the Contracting Officer's Representative (COR) 1) executive summaries, 2) technical progress reports, and 3) Standard Data Submission covering the work accomplished during each monthly reporting period. By the expiration date of the contract, the Contractor shall submit a comprehensive draft and revised Final Report. Reports shall be submitted electronically via e-mail to the COR, CO and any others they designate. Two hard copies shall be submitted to the CO. Any attachments to the e-mail report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft Project or Microsoft PowerPoint or other file types compatible with the Microsoft Office suite of products. Specialized files can be submitted with prior discussion.

1) Monthly Executive Summary:

On the fifteenth (15th) of each month for the previous calendar month the Contractor shall submit a Monthly Executive Summary to the COTR and the CO. A copy of the summary will also be sent to the following email address: BardaTrackingToolInfo@hhs.gov. The executive summary will be formatted as a Microsoft Power Point presentation and will include the following:

Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission.

Project Progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets

Project Issues presented headings and each item as a talking point bullet.

2) Monthly Technical Progress Reports:

On the fifteenth (15th) of each month the Contractor shall submit a report to the COR and the CO describing work accomplished in the previous calendar month. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. Technical Progress Reports will include baseline and updated project timelines, milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail to the COR, CO and the following email address: BardaTrackingToolInfo@hhs.gov. Such reports shall include the following specific information:

Title page- containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Introduction/Background - An introduction covering the purpose and scope of the contract effort.

Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period.

Task Orders - Discuss each open Task Order; describe the technical progress and issues.

Issues - Issues resolved, new issues and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned are to be furnished. Revised timelines are provided.

Contractual Issues- Include an updated table of contractual issues with columns for Issue Number, Task Order, Issue Description, Date of Initial Request, Impact, Status/Comment.

Invoices – Summary of any invoices submitted during the reporting period. Include an updated table with columns for Invoice number, Date Submitted, Amount, Activity/Comments and Date paid. The summary invoice table should include all invoices to date of the report.

Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.

Summary - Include an updated table with columns for Task Order, Description, Period of Performance and Current Status. The summary table should contain all task orders since award

Distribution List – A list of persons receiving the Technical Progress report.

Attachments – Results on the project are provided as attachments.

3) Standard Data Submissions:

Standard Data Submissions is the electronic transfer of manufacturing and supply chain data sets from the contractor's automated information management systems or other data sources and files directly to a secure data capture system known as the BARDA Tracking Tool.

The Contractor(s) shall submit the following data sets to the BARDA Tracking Tool within three months of award.

Data Set Number	Description	Aligns with CLIN #
MN001	Seed Development, Selection and Production	CLIN #0001
MN004	Production of cGMP Bulk Drug Substance	CLIN #0004
MN007	Formulation, Fill and Finish of Final Drug Product	CLIN #0006
MN014	Stability Information / Studies of Bulk Drug	CLIN #0007

	Substance	
MN017	Stability Information / Studies of Final Drug Product	CLIN #0007
DM002	Domestic Shipment of Final Drug Product	CLIN#0008

Instructions for connecting with the BTT will be provided at Contract Award.

Instructions for preparing data sets are defined in 'Section L, Attachments A'

New data sets will be communicated in future 'Requests for Task Order Response' under CLIN 15.

4) Monthly Teleconference – A monthly teleconference to review the content of the written monthly report. The Contractor shall provide minutes for the monthly teleconference with the next monthly report.

5) Contract Final Reports:

By the expiration date of the contract, the Contractor shall submit a comprehensive Final Report that shall detail, document, and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the COR for review and revision, then the original, four copies, and an electronic file containing the Final Report with revisions shall be submitted to the COR for distribution to the CO and the Program.

Table 1 - Final Report Requirements:

	CLIN 0001 MVS/WVS	CLIN 0002 Development Lot(s)	CLIN 0003 Clinical Lots	CLIN 0004 Antigen Commercial lots	CLIN 0005 Adjuvant Commercial Bulk lot(s)	CLIN 0006 Formulation and filling	CLIN 0007 Storage and Stability	CLIN 0008 Shipping	CLIN 009 Candidate Vaccine Virus	CLIN 0010 Potency Reag. and Stand. Mnfcg and Testing	CLIN 0011 Laboratory Testing	CLIN 0012 Animal Tests	CLIN 0013 Clinical Tests	CLIN 0014 Disposal of product	CLIN 0015 Standard Data Submissions	CLIN 0016 Additional Reporting
Manufacturing location (building, room, city/country)	x	x	x	x	x	x			x	x						
Dates of major manufacturing steps	x	x	x	x					x	x						
Major process inputs (# eggs, bioreactor size/working volume, cell bank#, CVV, MVS/WVS, lot number)	x	x	x	x	x	x	x		x	x						
Volume (volume produced, lot size, quantity/number)	x	x	x	x	x	x				x						
Antigen yields (e.g. µg/ml, ffu/ml))		x	x	x		x				x						
Manufacturing deviations	x	x	x	x	x	x			x							
Certificates of Analysis (in English)	x	x	x	x		x										
CBER Identity certification letter	x															
Storage location and inventory (building, room, refrigerator, shelf)	x	x	x	x	x				x	x						
Pictures of produced material clearly marked with an appropriate US Government Property label	x	x	x	x	x	x										
Final Pre-Clinical Study Report												x				
Final Clinical Study Report													x			
Clinical Study Database													x			
CBER Lot release letter for licensed products				x												
Stability or other testing results	x	x	x	x	x	x	x		x		x					
Final report at the end of the POP	x	x	x	x	x	x	x	x	x	x	x	x	x	x		

SECTION L: Instructions - Technical Proposal Instructions

General

Proposals should not use fonts smaller than 10 points. Page margins should be no less than 1". Technical proposals should be no more than 75 pages.

To aide effective evaluation, it is requested that Offerors provide the name of the Principal Investigator (PI)/Project Director responsible for the overall implementation of the contract and Co-investigators and key contacts for technical aspects of the project. Describe the qualifications, experience, and accomplishments of the PI and Co-investigators of the Offeror and Subcontractors. Include, in an attachment, curricula vitae of supervisors and key technical personnel, and the approximate percentage of time each will be available for this program.

Do not include social security numbers or other personal identifiable data on the curriculum vitae or any other documents.

The proposal should describe the experience and qualifications of other personnel who will be assigned to work on this program. Using organizational charts show the composition of task or work groups by project area. Document the general qualifications of work groups and recent experience with similar programs. A clear description and schematic of the Offeror's project organization including subcontractors.

The proposal should list names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. Indicate the technical areas, character, and extent of subcontract or consultant activities and anticipated sources. For all proposed personnel who are not currently members of Offeror's staff, provide a letter of commitment or other evidence of availability. The letter of commitment must at a minimum include (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a consultant and (4) how rights to publication and patents will be handled.

For all CLINs

The proposal shall include:

- A Contractor's Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget specifying activities to be supported by the government. The level of detail contained in the CWP and the corresponding Gantt chart should be sufficient to facilitate management and execution of the contract by the successful Offeror(s).
- A Gantt chart describing the timeline from task order award thru completion.
- For facilities proposed for execution of work under this contract, copies of inspection reports from the last three years provided by regulatory authorities following GMP inspections of the facility they are proposing to use, or b) if no

inspections have taken place, a statement to that effect. These reports will be part of the Technical Appendices and will not count as part of the page limit.

SECTION L: 'ATTACHMENTS'

Attachment A – Standard Data Formats and Instructions -

Attachment B – BARDA – request for shipment

Attachment C – Standard Personnel

ATTACHMENT "A" - Instructions for Preparing and Submitting Standard Data Sets

Standard Data Submissions is the electronic transfer of manufacturing and supply chain data sets from the contractor's automated information management systems or other data sources directly to another automated information management system. BARDA's secure data capture system is known as the BARDA Tracking Tool or BTT.

The BTT capitalizes on the lessons learned from the 2009 H1N1 Pandemic Influenza campaign during which extensive manual effort and precious time was expended to communicate and manage a response. By defining and standardizing data sets that represent key elements of manufacturing and supply chain activities, BARDA aims to significantly reduce the management burden and enhance the efficiencies in communications by taking advantage of current technologies and applications.

Contractors will be expected to submit data sets as defined in the formats detailed below. These data sets form the baseline for automated reporting. New data sets that are generated through CLIN #0015 requirements become part of baseline once they are tested and validated.

Baseline Datasets

Data Set Number	Description
MN001	Seed Development, Selection and Production
MN004	Production of cGMP Bulk Drug Substance
MN007	Formulation, Fill and Finish of Final Drug Product
MN014	Stability Information / Studies of Bulk Drug Substance
MN017	Stability Information / Studies of Final Drug Product
DM002	Domestic Shipment of Final Drug Product

Submission Instructions:

In general, data set files will be transmitted to the BTT whenever there is a change or update in the data. New files will overwrite existing files such that the latest file submitted represents the most current information. The only exception to the overwrite rule are submissions for MN014 and MN017. Only new data will be reported for MN014 and MN017.

All files that are submitted to the BTT will go through an error check step prior to processing. A comprehensive list of error checking/validation processes will be provided at contract award.

All data sets have primary key fields that must never be NULL. Some fields have a two-step primary key system. In these cases if certain data objects are non-null, then additional primary key fields become necessary. These details are provided for each data set.

Details on how to submit data / connect with the BTT will be provided at contract award.

Baseline Data set descriptions are identified in the following pages.

MN001 Seed Development, Selection and Production

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	varchar	5		PK	no	MN001	MN001
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	N/A	0002
Strain	Strain	Vaccine strain	varchar	7			no	N/A	H1N1
Subtype_Wildtype	Strain Subtype Wild Type	Strain / Subtype: Wild Type Virus Name	varchar	100			no	N/A	A/California/08/2009 (H1N1)
Subtype_Candidate	Strain Subtype Candidate	Strain / Subtype: Candidate Vaccine Virus Name	varchar	150			no	N/A	A/California/08/2009 (H1N1)
Candidate_Recv_Date	Candidate Seed Recv Date	Date Seed Candidate Received	datetime				no	N/A	2013.01.01 12:00:00.000
Recv_From	Received From	Received From	varchar	255			no	N/A	
Seed_Prod_Date	Seed Produced Date	Date Seed Produced	datetime				yes	null	2013.01.01
Seed_Sent_Date	Working Seed Send Date	Date Working Seed Sent to FDA	datetime				yes	null	2013.01.01
Seed_Cert_Date	Working Seed Certification Date	Date of FDA Certification of Working Seed	datetime				yes	null	2013.01.01
Seed_Concur_Date	Working Seed Concurrence Date	Date of CDC Concurrence of Working Seed	datetime				yes	null	2013.01.01
Seed_SKU	Seed SKU	Seed Stock Keeping Unit	varchar	30			yes	null	
Seed_SKU_Descr	Seed SKU Description	Seed Stock Keeping Unit Description	varchar	255			yes	null	2013.01.01
Seed_Lot_Num	Seed Lot #	Seed Lot #	varchar	30		PK	yes	null	HH100738 01A
Site_Loc	Site Location	Site Location	varchar	300			no	null	1600 Pennsylvania Ave., NW, Washington, D.C. 20500, USA
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

If dates are reported for seed production, send to FDA, certification, or concurrence then Seed Lot # becomes part of the primary key. It should be filled in w ith a non-null <blank> string until data is available.

MN004 Production of cGMP Bulk Drug Substance

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	varchar	5		PK	no	MN004	MN004
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	-1	0002
Strain	Strain	Vaccine strain	varchar	7			no	N/A	H1N1
Subtype	Subtype	Strain / Subtype: Wild Type Virus Name	varchar	100			no	N/A	A/California/08/2009 (H1N1)
Seed_Lot_Num	Seed Lot #	Vaccine Seed Manufacturer Lot #	varchar	30			no	N/A	HH10001
HA_Submit_Date	Purified HA Submit Date	Date Purified HA (Bromelainted Bulk) submitted to FDA	datetime				yes	null	2013.01.01
HA_Ack_Date	Purified HA Acknow ledgement Date	Date Purified HA (Bromelainted Bulk) acknow ledged by FDA	datetime				yes	null	2013.01.01
HA_Target_Antisera_Date	Purified HA Target Antisera Date	Target Date of Purified HA (Bromelainted Bulk) Completion - Sheep Antisera	datetime				yes	null	2013.01.01
HA_Actual_Antisera_Date	Purified HA Actual Antisera Date	Actual Date of Purified HA (Bromelainted Bulk) Completion - Sheep Antisera	datetime				yes	null	2013.01.01
SRID_Receive_Date	SRID Reagent Received Date	Date Standardized (SRID) calibarated reagent received from FDA	datetime				yes	null	2013.01.01
LYO_Receive_Date	LYO Antigen Receive Date	Date Calibrated (lyo) reference antigen received from FDA	datetime				yes	null	2013.01.01
BDS_Submit_date	Bulk Drug Substance Submit Date	Date Comparator Bulk Drug Substance (BDS) Lots submitted to FDA	datetime				yes	null	2013.01.01
BDS_SKU	BDS_SKU	Stock Keeping Unit	varchar	30		PK	no	N/A	HHVN200001
SKU_Descr	SKU Description	Stock Keeping Unit Description	varchar	255			no	N/A	Influenza A (H1N1) 2009 Monovalent Vaccine Bulk Drug Substance
BDS_Lot_Num	BDS Lot #	Bulk Drug Substance Manufacturer Lot #	varchar	30		PK	no	N/A	HH100738 01A
Vol_On_Hand	Volume On Hand	Volume on hand (in Liters)	decimal	6	2		yes	0	123456.12
Exp_Date	Expiration Date	Expiration Date	date				yes	null	2013.01.01
BDS_Mfg_Loc	BDS Manufacturing Location	Bulk Drug Substance Manufacturing Location	varchar	300		PK	yes	null	1600 Pennsylvania Ave., NW, Washington, D.C. 20500, USA
Mfg_Start_Date	Mfg Start Date	Manufacturing Start Date	datetime				yes	null	2013.01.01
Dose_Yield_Alt	Dose Yield Alternative Assay	Dose Yield (Alternative assay mcg/ml - LAIV Alternative Assay)	decimal	6	2		yes	null	1234.18
Dose_Yield_Final	Dose Yield Final Assay	Dose Yield Final Assay (mcg/ml) - LAIV Final Assay (FFU)	decimal	12	2		yes	null	
Scrap_Factor	Scrap / Loss Factor	Scrap / Line Loss Factor	decimal	4	2		yes	null	0000.12
Int_Lot_Release_Date	Internal Lot Release Date	Internal Lot Release Date	datetime				yes	null	2013.01.01
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

If Internal Lot Release Date contains data (is non-null) then Vol on Hand and either Dose_Yield_Final or Dose_Yield_Alt become required. CHECK IN ETL.

MN007 Formulation, Fill and Finish of Final Drug Product

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	varchar	5		PK	no	MN007	MN007
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	-1	0002
Strain	Strain	Vaccine strain	varchar	7			no	N/A	H1N1
Subtype	Subtype	Strain / Subtype: Wild Type Virus Name	varchar	100			no	N/A	A/California/08/2009 (H1N1)
Label_Submit_Date	FDA Label Submission Date	FDA Draft Label Submission	datetime				yes	null	2013.01.01
Requested_Approval_Date	Requested Label Approve Date	Requested FDA Label Approval Date	datetime				yes	null	2013.01.01
Actual_Approval_Date	Label Approve Date	FDA Label Approval Date	datetime				yes	null	2013.01.01
Dose_Target	Dose Target	Formulation (Dose) Target	decimal	12	2		yes	null	15.00
Dose_Target_Units	Dose Target Units	Forulation (Dose) Target Units of Measure	varchar	12			yes	null	mg, mcg
Fill_Start_Date	Date of Fill Start	Date of Fill Start	datetime				no	N/A	2013.01.01
Fill_Complete_Date	Date of Fill Completion	Date of Fill Completion	datetime				yes	null	2013.01.01
Fill_SKU	Fill SKU	Fill Stock Keeping Unit	varchar	30			no	N/A	HHNV300001
Fill_Lot_Num	Fill Lot #	Fill Lot #	varchar	30		PK	no	N/A	
GTIN	GTIN	Global Trade Item Number	varchar	14			yes	null	00066521200107
NDC	NDC	NDC	varchar	13			yes	N/A	66521-200-10
Brand_Name	Brand / Trade Name	Brand / Trade Name	varchar	255			yes	null	Influenza A (H1N1) 2009 Monovalent Vaccine 5mL multidose vial
Sales_Unit	Unit of Sale	Unit of Sale	varchar	50			yes	null	10 pack - 1 dose sprayer (Intranasal)
Pkg_Qty	Package Qty per Unit of Sale	Package Quantity per Unit of Sale	int				yes	null	1
Fill_Qty	Fill Qty (of Units of Sale)	Filled Quantity of Units of Sale	int				yes	null	745
FDP_Lot_Num	Finish / FDP Lot #	Finish / Finished Drug Product Lot #	varchar	30			yes	N/A	101716 P1
FDP_Qty	Finish / FDP Qty	Finish / Finished Drug Product Quantity	int				yes	null	1, 2, 3…
FDA_Lot_Submit_Date	FDA Lot Submission Date	FDA Lot Submission Date	datetime				yes	null	2013.01.01
FDA_Lot_Approve_Date	FDA Lot Approval Date	FDA Lot Approval Date	datetime				yes	null	2013.01.01
Exp_Date	Expiration Date	Expiration Date	datetime				yes	null	2013.01.01
Mfg_Loc	Manufacture Location	Manufacture Location	varchar	300			no	N/A	1600 Pennsylvania Ave., NW, Washington, D.C. 20500, USA
Mfg_Date	Manufacture Date	Manufacture Date	datetime				no	N/A	2013.01.01
Mfg_Release_Date	Manufacturer Release Date	Manufacturer Release Date	datetime				yes	null	2013.01.01
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

If FDP_Lot_Num is not null, all fields in blue become required. PERFORM CHECK IN ETL, not database.

If Mfg_Release Date is not null, all fields except fields in red become required. PERFORM CHECK IN ETL, not database.

MN014 Stability Information / Studies of Bulk Drug Substance

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	varchar	5		PK	no	MN014	MN014
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	-1	0002
Strain	Strain	Vaccine strain	varchar	7			no	N/A	H1N1
Subtype	Subtype	Strain / Subtype: Wild Type Virus Name	varchar	150			no	N/A	A/California/08/2009 (H1N1)
BDS_Lot_Num	BDS Lot #	Bulk Drug Substance Mfg Lot Number	varchar	30		PK	no	N/A	
Stability_Date	Stability Date	Date of the Stability Study Information	datetime			PK	no	N/A	2013.01.01
Stability_Value	Stability Value	Measured Stability Value for this BDS Lot (in mcg/ml)	decimal	12	2		no	-1.00	246.26
Stability_Study_Num	Stability Study #	Stability Study Number	varchar	50		PK	no	N/A	
Stability_Study_Descr	Stability Study Description	Stability Study Description	varchar	255			no	N/A	
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

MN017 Stability Information / Studies of Final Drug Product

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	varchar	5		PK	no	MN017	MN017
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	-1	0002
Strain	Strain	Vaccine strain	varchar	7			no	N/A	H1N1
Subtype	Subtype	Strain / Subtype: Wild Type Virus Name	varchar	150			no	N/A	A/California/08/2009 (H1N1)
FDP_Lot_Num	FDP Lot #	Finished Drug Product Mfg Lot Number	varchar	30		PK	no	N/A	
Stability_Date	Stability Date	Date of the Stability Study Information	datetime			PK	no	N/A	2013.01.01
Stability_Value	Stability Value	Measured Stability Value for this FDP Lot (in mcg/ml)	decimal	12	2		no	-1.00	246.26
Stability_Study_Num	Stability Study #	Stability Study Number	varchar	50		PK	no	N/A	
Stability_Study_Descr	Stability Study Description	Stability Study Description	varchar	255			no	N/A	
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

DM002 Domestic Shipment of Final Drug Product

Column Name	Display Name	Description	Datatype	Size	Precision	Key?	NULL?	Default Value	Example Values
Activity_Type	Activity Type	Activity Type Code for data received from manufacturer	char	5		PK	no	DM002	DM002
Report_Date	Data Reported as of	Date/Time activity data w as received from manufacturer	datetime			PK	no	Today	2013.01.01 12:00:00.000
Contract_Num	Contract #	Contract number for data received from manufacturer	varchar	50		PK	no	N/A	HHSO100200800072I
CLIN_Num	CLIN	Contract Line Item number for data received from manufacturer	varchar	5			no	-1	0002
BOL_ID	BOL Shipment ID	Bill of Lading Shipment ID	varchar	30		PK	no	N/A	
Ship_From	Ship From	Ship From Location	varchar	255			no	N/A	Atlanta, GA
Consignee	Consignee	Consignee Name	varchar	255			no	N/A	
Ship_To	Ship To	Ship to Destination Address	varchar	255			no	N/A	Modesto, CA
Carrier_Name	Carrier Name	Carrier Name	varchar	75			no	N/A	
Carrier_Code	Carrier Alpha Code	Standard Carrier Alpha Code	varchar	4			yes	N/A	
Trailer_Num	Trailer Number	Trailer Number	varchar	25			yes	null	
Seal_Num	Seal Number	Seal Number	varchar	25			yes	null	
Shipment_Date	Shipment Date	Goods Issue / Shipment Date	datetime				no	N/A	
Packing_ID	Packing List ID	Delivery / Packing List ID #	varchar	50			yes	null	
Customer_PO	Customer PO #	Customer PO #	varchar	50		PK	no	N/A	
NDC	NDC	NDC	varchar	13			no	N/A	66521-200-10
Qty	Quantity	Shipment Quantity	int				no	N/A	
Lot_Num	Lot Number	Lot Number	varchar	30		PK	no	N/A	
Exp_Date	Expiration Date	Expiration Date	datetime				yes	null	2013.01.01
Remarks	Remarks	Remarks	varchar	MAX			yes	null	

ATTACHMENT "B" – BARDA Influenza Division Vaccine Request Form

BARDA Influenza Division Vaccine Request Form

Reason for Shipment: _____

Shipping Origin Location: _____

A. Vaccine Request

Agent Requested: _____

No. of Vials Requested: _____

Requester Signature: _____ Date: _____

Shipping Address:

B. Investigational Agent Shipment.

Complete the section below send with vaccine to shipping address listed above

Dosage Form: _____ Volume Per Vial: _____

No. of Vials Shipped: _____ Lot No.: _____ Shipment Date:_____

Shipment Conditions (Check all applicable boxes):

☐ Cool Packs ☐ Temperature Monitor

_____ _____

Signature Date/Time Shipped

C. Investigational Agent Receipt Verification

Complete the section below upon receipt and scan this form to BARDA ID (Attention: xxx.xxx@hhs.gov)

No. of Vials Received: _____ Temperature of Shipment Received: _____

Receipt Condition: ☐ Intact ☐ Damaged

_____ _____

Signature Date/Time of Receipt

ATTACHMENT "C" Technical Personnel Rates

For 'Cost' CLINs-Labor hours

Offerors should provide a table of position titles, description of the education level attained and years of relevant experience, and hourly rates. Responses to unpriced CLINs will rely on these tables to evaluate proposed costs. For example:

Position	Description	Hourly Rate
QA-1	B, 3+ years	$
QA-2	B, 6+ years; M, 3+ years	$
QA-Manager	B, 18+ years; M, 12+ years; D, 6+ years	$
QA-Director	D, 16+ years	$
QA-VP	D, 20+ years	$
Technician-1	H, 6+ years	$

H: High School; B: Bachelor; M: Master; D: Doctor

Offerors should provide over-head rates specific to the facilities offered.